

# Global Collaboration on Biotechnology Risk Assessment

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## Introduction

The governments of Canada and the United States have similar responsibilities for evaluating new biotechnology products. In response to a perceived need for guidance on obtaining the best possible identifications of product organisms, a key element of the evaluations, Health Canada has sponsored a collaborative study of identification methods used for pseudomonads, which are frequently employed for biotechnology purposes. An diverse group of laboratories, geographically, institutionally and methodologically, were recruited to identify cultures of pseudomonads supplied as unknowns, and evaluations were made of the success of the methods used. This report describes of the organization of the collaboration and uses of the results by the participating organizations.

## History

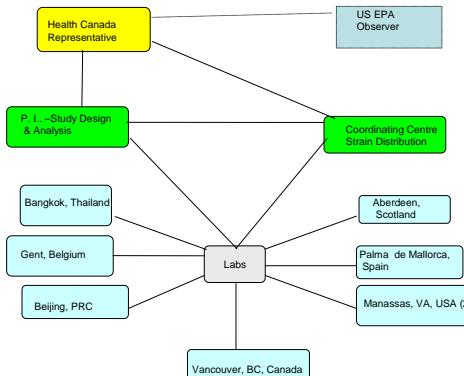
EPA/OPPT is required to perform microbial risk assessments (MRAs) when evaluating new biotechnology products under the Toxic Substances Control Act (TSCA). A key element of any MRA is identification of the microorganism. The species concept for bacteria is complex and somewhat fuzzy. This makes identification of important biotechnology organisms, like pseudomonads, anything but straightforward. EPA has sought assistance in developing approaches to microbial identification for MRAs.

- IAGs with NIH beginning in 1984
- Cooperative agreement with ATCC
  - CR821484
  - 1993-1997
  - Included Environment Canada (EC) and Ag.-Agr. Food Canada (CFIA) participation.
  - Held workshop with international researchers
  - Recommended lab study followup
- Health Canada (HC) initiates followup lab project
  - EPA invited as observer/participant in reciprocation for Canadian participation in EPA project

## How the Collaboration Helps All Participants

- HC Provides Funding Support
- Meetings held at participating lab venues with HC support
- EPA Project Officer (PO) from previous Co-op invited to chair meetings
- EPA shares some transportation costs for EPA PO
- Data Analyses
- HC funds main analyses by HC Contractor for HC MRA primary use
- EPA PO has early access to data for independent analyses
- EPA analyses focus on use of data for EPA biotech MRAs
- EPA and HC analyses both included in publications
- Other participating governments' labs get data for own use in public health
- Culture collections get insight into identifications of their own cultures

## Project Organization



## Status

- "Double-Blind" study funded in 4/2000; Project kickoff 3/2001
  - Recruited labs involved in Pseudomonas identification and taxonomy
  - 8 locations; 3 continents
  - 2 government; 3 university; 1 hospital; 2 culture collection labs
  - 18 methods/approaches compared
- EPA Project Officer from previous Co-op invited to chair meetings, analyze data
- EPA gets access to data from project before publication
- Phase I completed 2003
  - 25 species; ~300 cultures identified
  - Posters at 4 international scientific meetings
  - Several publications in preparation for peer-reviewed journals.
- Phase II underway
  - ~250 cultures being identified
  - More methods being used
  - Different species being analyzed

## Next Steps

- Phase II still "blind"; codes to be broken in 2006
  - Results to be analyzed as for Phase I
  - Additional publications projected
  - Data applied to TSCA reviews as needed
  - Results transmitted to OECD Microorganisms Sub-working group of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology
  - Post 2006 research follow-on under discussion



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